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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Timothy Devine
Co-Owner
Devine Farms, LLC
2839 New Boston Rd.
Canastota, NY 13032-4394

June 4, 2004

NYK-2004-17

Dear Mr. Devine:

Between January 20 and February 4, 2004, a U.S. Food and Drug Administration investigator conducted an inspection at your farm located in Canastota, New York. This inspection confirmed that you offered two animals for sale for food that were adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused medicated feeds to be adulterated within the meaning of Section 501(a)(6) of the Act.

On or about October 23, 2003, you offered for sale a calf identified with sale tag [redacted] for slaughter as human food. The calf was sold to and slaughtered at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 3.51 ppm neomycin in kidney tissue.

On or about November 17, 2003, you offered for sale a calf identified with sale tag [redacted] for slaughter as human food. The calf was sold to and slaughtered at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 0.43 ppm neomycin in kidney tissue.

There is no established tolerance for neomycin in calves (Title 21 Code of Federal Regulations, Section 556.430). The presence of this drug at the level reported in these animals causes the food to be adulterated.

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs and medicated feeds are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit

depletion of potentially hazardous drug residues from edible tissues. For example, you failed to record the treatment of calves [redacted] and #[redacted] Foods from animals held under such conditions are adulterated under Section 402(a)(4).

You are adulterating the medicated feeds [redacted] and [redacted], Calf Milk Replacers, which contain neomycin, when you used them in calves to be processed for veal contrary to the warning on their labels. Since the Act does not permit the extralabel use of medicated feeds, your actions cause these medicated feeds to be unsafe to use under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,

Jerome G. Woyshner
District Director